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(54) Mask cushion and method of using same

(57) A nasal CPAP treatment apparatus is disclosed with a flow generator coupled to a nasal mask. The mask has a nasal cushion forming a nose-receiving cavity. The cushion has a triangularly-shaped frame of resilient material with a mask engaging portion connected by a side wall to a face engaging portion which has a nasal bridge region, a cheek region and a lip region. The cushion may have a portion of the side wall in the nasal bridge region being other than straight to provide an improved sealing in the nasal bridge region. A plurality of membranes, preferably three, of resilient material extend substantially around the triangularly-shaped frame. Some of the membranes are thicker in the lip region than in the nasal bridge region to improve fit of the cushion in use.

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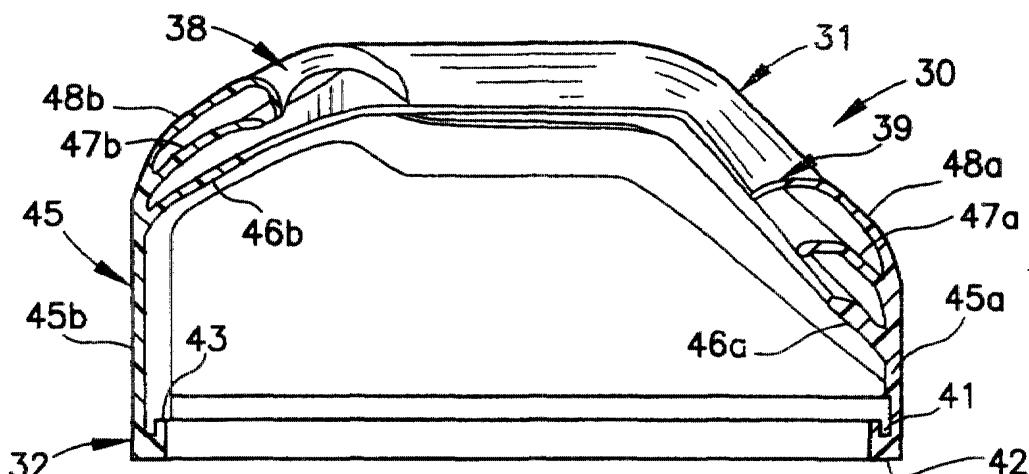


FIG. 6

Description

[0001] The present invention relates to an improved cushion that contacts a portion of a patient's face to provide a comfortable interface and improved seal between an external device, such as a respiratory mask, and the patient.

[0002] A variety of respiratory masks are known having a flexible seal that covers the area surrounding the nose and/or mouth of a human user and that are designed to create a continuous seal against the user's face.

[0003] Because of the sealing effect created, gases can be provided at a positive pressure within the mask for consumption by the user. The uses of such masks include, but are not limited to high altitude breathing (aviation applications), swimming, mining and fire fighting applications along with various medical diagnostic and therapeutic applications.

[0004] One requisite of many of these masks, particularly medical respiratory masks, is that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in conventional mask configurations, the mask-to-face seal has been attained in many instances only with considerable discomfort for the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear the mask continuously for hours or perhaps even days. In such situations, the user will not tolerate an uncomfortable mask for long durations and optimum therapeutic or diagnostic objectives will not be achieved if imperfect seals are formed, or will be achieved with great difficulty and considerable user discomfort.

[0005] Nasal masks are commonly used in the treatment of respiratory conditions and sleep disorders (e.g., obstructive sleep apnea) by delivering a flow of breathable gas for, or to assist patient respiration. These nasal masks typically receive a gas supply line which delivers gas into a chamber formed by walls of the mask and the user's face. The walls usually are semi-rigid and have a face contacting portion including an aperture which is aligned with the wearer's nostrils. The face contacting portion can comprise a soft, resilient elastomeric material which may conform to various facial contours. The mask normally is secured to the wearer's head by straps. The straps are adjusted to pull the mask against the face with sufficient force to achieve a gas tight seal between the mask and the wearer's face but not so tight as to be uncomfortable. Gas is thus delivered to the mask and into the wearer's nasal passages.

[0006] Problems often arise with masks of the above configuration. For example, the mask may be dislodged, thereby breaking the seal between the mask and wearer. This may occur if the wearer rolls over when sleeping thereby creating a drag force on the gas supply line which is transmitted to the mask, breaking the seal. In the case of a mask being used for the administration of

Continuous Positive Airway Pressure (CPAP) treatment for the condition obstructive sleep apnea, such a leak can result in the pressure supplied to the entrance of the wearer's airway being below the therapeutic value, and the treatment becoming ineffective.

[0007] Another problem is the face contacting portion may apply excessive pressure to the wearer's face resulting in discomfort and possibly skin irritation. This can occur because the face contacting portion has to distort beyond its normal range of elasticity to conform to certain facial contours which requires the application of excessive forces. In some cases these excessive pressures and forces may cause the face to distort to conform with the face contacting portion to increase wearer discomfort, resulting in facial soreness and ulceration.

[0008] An example of the respiratory mask useful in the CPAP treatment is in US-A-6,112,746 issued to Kwok et al. September 5, 2000, the entire disclosure of which is incorporated by reference. That patent lists over 200 pieces of prior art generally pertinent to the subject invention. The present invention relates to a cushion for a respiratory mask which is more comfortable and provides a superior seal than heretofore available.

[0009] These and other advantages will be described in more detail below.

[0010] Accordingly, it is an object of the present invention to provide an improved cushion effecting an superior seal for confronting engagement with the surface of the users face to form a sealed interface therewith that overcomes the shortcomings of conventional seal techniques. This object is achieved, according to one embodiment of the present invention, by providing a cushion in which three membranes are used to provide superior sealing characteristics while minimizing the head strap tension and therefore the compressive forces exerted by the mask against the user's face.

[0011] Another object of the present invention is to provide a respiratory mask with an improved cushion wherein the cushion is provided with membranes having variable thicknesses between the nasal bridge region and the region that fits between the nares and the upper lip to provide superior sealing characteristics.

[0012] Yet another object of the invention is to provide a mask cushion having a side wall that is other than straight, such as curved or sinuous, which makes the cushion nose compressible to better fit around the user's face.

[0013] For the purpose of facilitating an understanding of the invention, there is illustrated in the accompanying drawings a preferred embodiment thereof, from an inspection of which, when considered in connection with the following description, the invention, its construction and operation, and many of its advantages should be readily understood and appreciated.

FIG. 1 is a side elevational view of a respiratory mask in accordance with the present invention

placed against the face of the user;

FIG. 2 is a front elevational view of the face side of the respiratory mask including the improved cushion of the present invention;

FIG. 3 is a perspective view of an embodiment of the improved cushion;

FIG. 4 is a perspective view of a cushion embodying the present invention;

FIG. 5 is a view like FIG. 4 rotated with respect to FIG. 4;

FIG. 6 is a cross-sectional view of one embodiment of the present invention as viewed along line A-A of FIG. 4;

FIG. 7 is a cross-sectional view of one embodiment of the present invention as seen along line B-B of FIG. 4;

FIG. 8 is a cross-sectional view of another embodiment of the present invention as seen along line A-A of Fig. 4;

FIG. 9 is a cross-sectional view of the embodiment of FIG. 8 as seen along line B-B of FIG. 4;

FIGS. 10A and 10B are views partly in section of an embodiment of the invention with an improved side wall; and

FIG. 11 is an elevational view partly in section of the embodiment of FIGS. 10A and 10B.

[0014] Referring now to the drawings and particularly FIGS. 1 and 2, there is shown a respiratory mask 10 which includes a rigid shell or cone 15 having a body portion 16. The body portion 16 in plan view is triangular in shape in order to fit the contours of a person's face above the nose to between the nose and the lips. The body portion has a rim 17 with outwardly extending tabs 18 for use with head straps to hold the mask to the users face which are not shown. The cone 15 has an end 20 defining a circular opening 21 to which is coupled a conduit 22 shown by broken line which connects a coupling 23 to the cone 15 and a gas source and flow generator 24. Upwardly extending from the cone 15 is a tab or frame member 25 having parallel vertically disposed slots 26 to accommodate portions of the head straps (not shown but well known in the art) which are used to affix the respiratory mask 10 to the user 36.

[0015] Referring now to FIGS. 3-8, there is shown a cushion 30 including the inventive seals or membranes for use in the respiratory mask 10 of the present invention. The cushion 30 includes an outer surface 31 having

a frame engaging portion 32 around the bottom periphery thereof and a face engaging portion 33. The cushion 30 defines a chamber 35 between the user 36 and the cone 15.

- 5 **[0016]** The cushion 30 further includes a nasal bridge region 38 positioned in use above the user's nose at the bridge portion thereof and a lip region 39 generally positioned in use between the nares of the nose and the lips. A cheek region 40 separates the nasal bridge region 38 and the lip region 39. The frame engaging portion 32 is relatively thick compared to the rest of the cushion 30 and defines a channel 41 in the frame engaging portion 32, the cushion 30 having a bottom surface 42 extending around the channel 41 being defined by an inner lip portion 43 and the tide wall 45 extending upwardly from the bottom surface 32 of the cushion. The channel 41 is sized to fit around the rim 17 of the rigid shell or cone 15 in order to securely mount the cushion 30 to the cone or shell 15.
- 10 **[0017]** Referring to FIGS. 6-7, there is shown a first embodiment of the present invention in which the side wall 45a near the lip region 39 of the cushion 30 is shorter than the side wall 45b near the nasal bridge region 38 of the cushion 30 to provide a better fitting cushion.
- 15 Near the lip region 39 of the cushion 30 there are three membranes integral with the side wall 45 and extending therefrom, the membranes being denoted as 46a, 47a and 48a. The membrane 46a is the thickest of the three membranes at the lip region 39 of the cushion 30. The membrane 47a is thinner than the membrane 46a at the lip region 39 and thicker than the outermost membrane 48a. The membranes 46,47, and 48 all have flexibility and deform when a force is applied against the cushion 30 when the cushion is in place against the users face
- 20 **[0018]** FIGS. 6 and 7 show the cushion 30 in section. As seen in FIG. 1. The use of three or more membranes is an improvement over the use of two membranes commonly used and seems to provide significant advances in comfort for the user. In the embodiment of FIGS. 6 and 7, the thicknesses of the membranes 46, 47 and 48 change between the lip region 39 of the cushion 30 and the nasal bridge region 38 of the cushion 30. The membranes 46b, 47, and 48b at the nasal bridge region 38 of the cushion 30 are all about the same thickness and all, preferably are as thin as the membrane
- 25 **[0019]** 48a at the lip region 39 of the cushion 30. At the lip region 39 the membranes have different thicknesses with, for instance membrane 46a being 1.524 mm (0.06 inches) thick, the membrane 47a being about 0.762 mm (0.03 inches) thick and membrane 48a being about 0.508 mm (0.02 inches) thick. The change in thickness of the membrane between the lip region 39 and the nasal bridge region 38 occurs in the cheek region 40. The advantages of the embodiment illustrated in FIGS. 6 and 7 as well as hereinafter is the use of the triple membrane system
- 30 **[0020]** in combination with the varying thickness in the membrane in order to provide not only a soft feeling cushion but also an improved seal. As seen in FIG. 4, the area labelled "c" corresponds to the cheek region 40 and is

the area where the membranes 46 and 47 are reduced in thickness until they all become the same thickness at the nasal bridge region 38 of the cushion 30. The area denoted in FIG. 4 as area "d" is the nasal bridge region 38 of the cushion 30 and it is in that region that the outer membrane 48b comes in contact with the bridge of the users nose and where for instance, the thickness of all membranes may be 0.508 mm (0.02 inches).

[0018] As seen from FIG. 6, the thickness of the side wall 45a just above the channel 41 may be just slightly thicker than the thickness of the inner membrane 46a. Thereafter, the thickness of the side wall 45 diminishes from the inner membrane 46 to the outer membrane 48. Finally, the side wall 45 becomes the outer membrane 48. Also, the side wall 45a may be thicker at the lip region 39 than at 45b in the nasal bridge region 38. The variable thicknesses in the membranes 46, 47 and 48 are a significant feature of the invention and provide a significant improvement in the comfort of cushion 30, in use.

[0019] Preferably, the cushion 30 is a single piece of moulded plastic and maybe removably or fixedly secured to the cone or shell 15 as by sonic welding, adhesives or any other suitable means. Silicon plastics are well known in the art.

[0020] Referring to FIGS. 8 and 9, there is shown another embodiment of the present invention in which cushion 130 is illustrated. Like numerals have been applied to like pieces with the exception that the embodiment of FIGS. 8 and 9 is identified with the corresponding number in the 100s. For instance, the outer surface of the cushion 130 is 131 as distinguished from the outer surface of the cushion 30 which is 31. The cushion 130 also has three membranes, the inner membrane 146, the middle membrane 147 and the outer membrane 148. The principal difference between the embodiments of FIGS. 6 and 7 and the embodiments of FIGS. 8 and 9 lies in the fact that the inner membrane 146 and the middle membrane 147 join to form a rib 149 connecting the membranes 146 and 147 to the side 145. Another difference in the embodiment of FIGS. 6 and 7 and the embodiment of FIGS. 8 and 9 is that the membranes 146, 147 and 148 do not change the thickness from the lip region 139 to the nasal bridge region 138.

[0021] Referring now to FIGS. 10A and 10B and 11, there is disclosed a third embodiment of the present invention which is similar to the embodiment disclosed in FIGS. 6 and 7 except that the side wall 150 has a portion 151 which is other than straight. In the embodiment illustrated in FIGS. 10A and 10B and 11, the portion 151 which is other than straight includes two arcuate portions 152 and 153 which are joined to each other to form a sinuous portion 151. Although a sinuous portion 151 is shown in FIGS. 10A and 10B and 11, other designs are intended to be incorporated herein and covered by the claims and include, by way of example only, simple arcuate portions, curved portions, V-shaped portions, box or rectangular shaped cross-sections or any other

than straight cross-section which provides a more compressible function to the side wall 150. The other than straight portion 151 of the side wall 150 is a significant improvement in the present invention in that the portion

- 5 151 is more compressible and provides a far improved sealing mechanism to the nasal bridge region of the cushion 30A. The remaining portions of the cushion 30A other than the side wall portion 151 is the same as shown in the embodiments illustrated in FIGS. 6 and 7.
- 10 10 However, preferably the side wall portion 45a in FIG. 6 is extended somewhat as shown in FIGS. 10A and 10B and 11 and provides an improved angle of contact when the cushion 30A is worn by a user; and in the preferred embodiment is 4.953 cm (1.95 inches) in the lip region and 5.461 cm (2.15 inches) in the nasal bridge region.
- 15 15 **[0022]** As illustrated in the drawings of FIGS. 10A and 10B and 11, the other than straight portion 151 extends in a horse shoe configuration around the nasal bridge region of the cushion 30A and extends approximately 2/3 of the way along the side wall 150 from the nasal bridge region into the cheek region and toward the lip region of the cushion 30A. Although as illustrated in FIGS. 10A and 10B and 11, the other than straight portion 151 does not completely encircle the cushion 30A, there is no particular reason that it may not. Accordingly, it is intended to cover within the invention herein disclosed, an other than straight portion 151 which extends entirely around the cushion 30A as well as the embodiment illustrated in which the other than straight portion 151 eventually blends into the straight side wall portion near the lip region.

- 20 25 **[0023]** FIGS. 10A and 10B contains many actual measurements from one preferred embodiment of the present invention, but are included only for purposes of illustration and not by way of limitation.

- 30 35 **[0024]** While there has been disclosed what is considered to be the preferred embodiment of the present invention, it is understood that various changes in the details may be made without departing from the spirit, or sacrificing any of the advantages of the present invention.

Claims

- 45 1. A nasal mask cushion (30) to sealingly connect a mask to a wearer's face, the cushion comprising: a substantially triangularly-shaped frame of resilient material having a mask engaging portion (32) and connected by a side wall to a face engaging portion (33) with a nasal bridge region (38), a cheek region (40) and a lip region (39); and a plurality of spaced apart and generally parallel membranes (46-48) of resilient material each having an inwardly extending rim with one of said membranes engaging a wearer's face in use.
- 50 55 2. A cushion according to claim 1, wherein there are

- three membranes (46-48).
3. A cushion according to claim 1, wherein said plurality of membranes comprise a first membrane (46) of resilient material having an inwardly extending rim substantially around said triangularly-shaped frame; a second membrane (47) of resilient material spaced from and generally parallel to said first membrane and having a second inwardly extending rim; and an outer membrane (48) of resilient material spaced from and generally parallel to said second membrane and having an outer inwardly extending rim, said outer membrane (48) engaging a wearer's face in use.
 4. A cushion according to claim 3, wherein at least a portion of the first membrane (46) is thicker than a portion of the second membrane (47).
 5. A cushion according to claim 3 or 4, wherein at least a portion of the first membrane (46) is thicker than a portion of the outer membrane (48).
 6. A cushion according to claim 3, 4 or 5, wherein at least a portion of the second membrane (47) is thicker than a portion of the outer membrane (48).
 7. A cushion according to any one of claims 4 to 6, wherein the portion of the membranes having different thickness are in the lip region.
 8. A cushion according to any one of claims 3 to 7, wherein at least a portion of the first and second membranes (46,47) have substantially the same thickness.
 9. A cushion according to claim 8, wherein the portions of the first and second membranes (46,47) having substantially the same thicknesses are in the nasal bridge region (38).
 10. A cushion according to any one of claims 3 to 9, wherein at least a portion of the first and outer membranes (46,48) have substantially the same thickness.
 11. A cushion according to claim 10, wherein the portions of the first and outer membranes (46,48) having substantially the same thickness are in the nasal bridge regions.
 12. A cushion according to any one of claims 3 to 11, wherein at least a portion of the second and outer membranes (47,48) have substantially the same thickness.
 13. A cushion according to claim 12, wherein the portions of the second and outer membranes (47,48)
 5. having substantially the same thickness are in the nasal bridge region (38).
 14. A cushion according to any one of claims 3 to 13, wherein at least a portion of the first and second and outer membranes (46-48) have substantially the same thickness.
 10. 15. A cushion according to claim 14, wherein the portions of the membranes having substantially the same thickness are in the nasal bridge region (38) and the portions of the membranes having different thicknesses are in the lip region (39).
 15. 16. A cushion according to any one of claims 3 to 15, wherein at least said first and second membranes (46,47) are thicker in the lip region (39) than said first and second and outer membranes (46-48) in the nasal bridge portion (38).
 20. 17. A cushion according to any one of claims 3 to 16, wherein said first and second membranes (46,47) are joined to one end of a common web having another end thereof joined to said side wall.
 25. 18. A cushion according to any one of the preceding claims, wherein a portion of the side wall in the lip region is thicker than a portion of the side wall in the nasal bridge region.
 30. 19. A cushion according to any one of the preceding claims, wherein the thickness of the outer membrane is substantially constant.
 35. 20. A cushion according to any one of the preceding claims, wherein the side wall in the lip region is shorter than the side wall in the nasal bridge region.
 40. 21. A cushion according to any one of the preceding claims, wherein said membranes are joined to said side wall.
 45. 22. A cushion according to any one of the preceding claims, wherein at least a portion of said side wall between said frame and the nasal bridge region is other than straight to provide an improved sealing in the nasal bridge region.
 50. 23. A cushion according to any one of claims 1 to 21, wherein a portion of said side wall in the nasal bridge region is other than straight to provide an improved sealing in the nasal bridge region.
 55. 24. A cushion according to claim 22 or 23, wherein the portion of said side wall that is other than straight is more compressible than at least a portion of said side wall between said frame and the lip region.

25. A cushion according to claim 22, 23 or 24, wherein
the portion of said side wall that is other than straight
is arcuate.
26. A cushion according to claim 22, 23 or 24, wherein
the portion of said side wall that is other than straight
is sinuous. 5
27. A nasal mask for connection to a wearer's face comprising: a mask body for connection with a supply
of breathable gas, and a nasal cushion according
to any one of the preceding claims secured to said
mask body, the body and cushion forming a nose-
receiving cavity. 10
28. A nasal CPAP treatment apparatus comprising: a
flow generator for the supply of gas at a pressure
elevated above atmospheric pressure; a gas delivery
conduit coupled to said flow generator; and a
nasal mask according to claim 27 in turn coupled to
said conduit to said nasal mask. 15 20
29. A nasal mask cushion to sealingly connect a mask
to a wearer's face, the cushion comprising: a sub-
stantially triangularly-shaped frame of resilient ma-
terial having a mask engaging portion and connect-
ed by a side wall to a face engaging portion with a
nasal bridge region, a cheek region and a lip region;
a first membrane of resilient material having an in-
wardly extending rim substantially around said tri-
angularly-shaped frame; one or more membranes
of resilient material spaced from and generally par-
allel to said first membrane and having inwardly ex-
tending rims; one of said One or more outer mem-
branes engaging a wearer's face in use, at least one
of said first or one or more membranes being thicker
in the lip region than said membranes in the nasal
bridge region. 25 30 35

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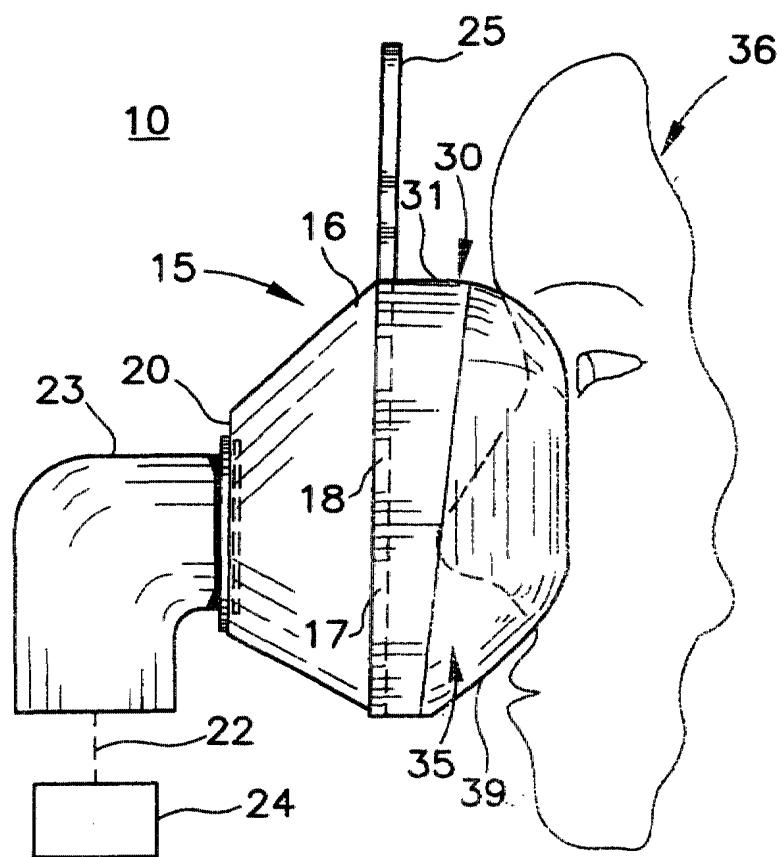


FIG. 1

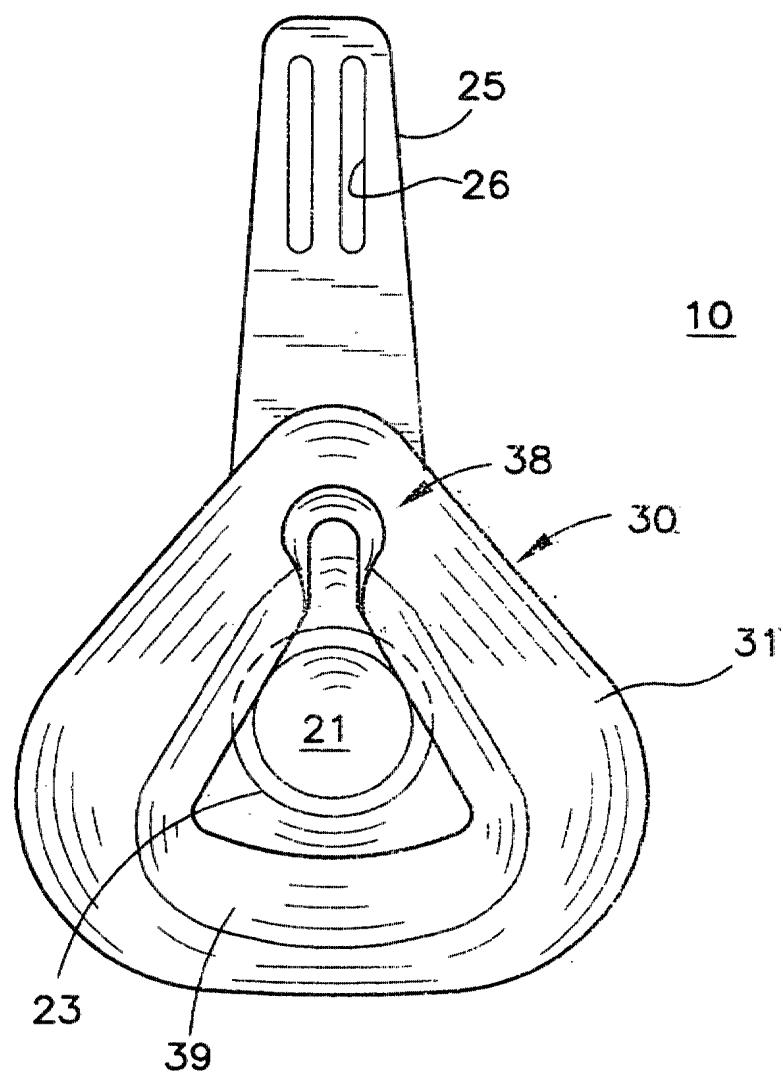


FIG. 2

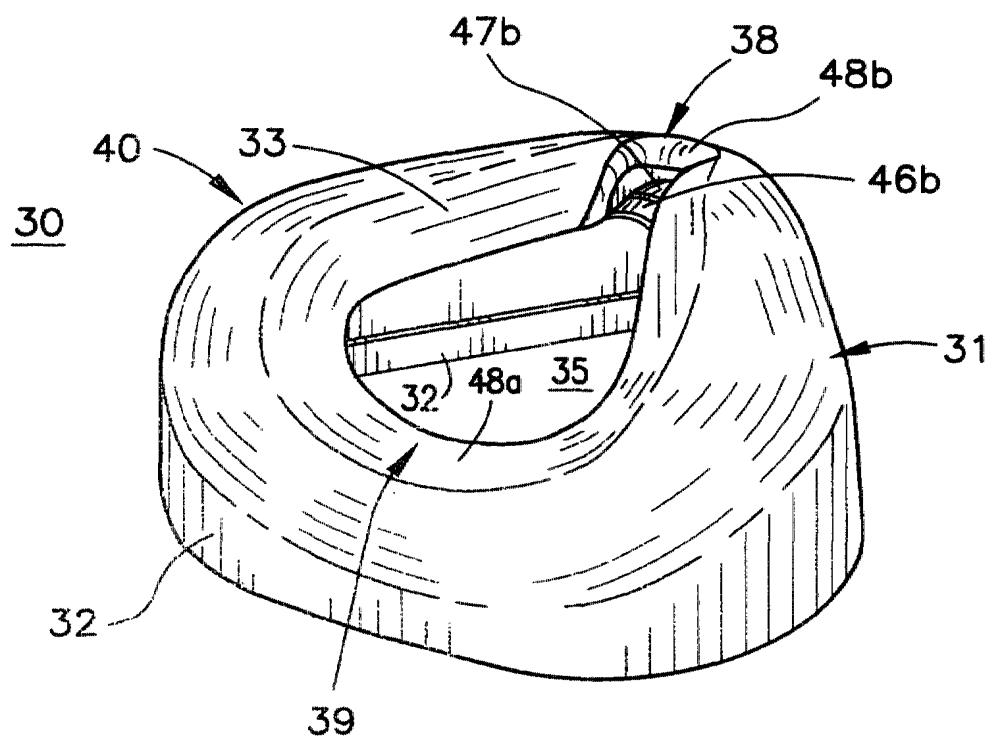


FIG. 3

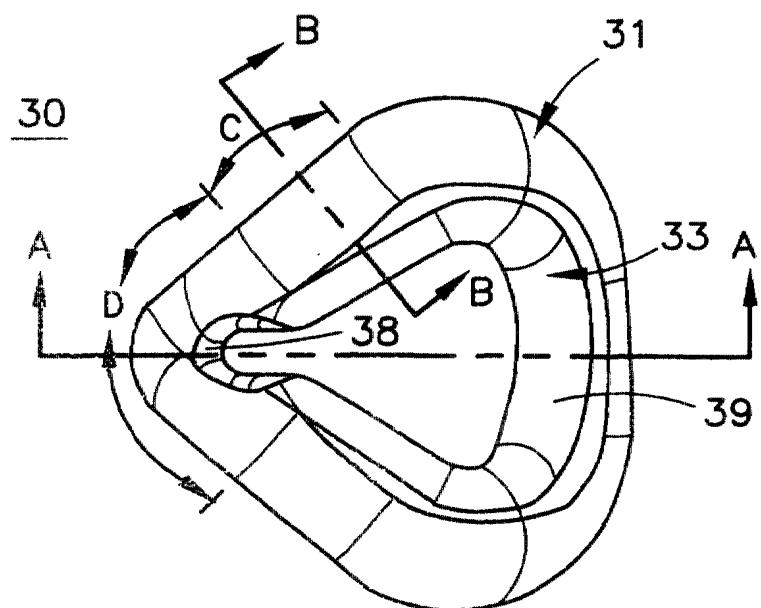


FIG. 4

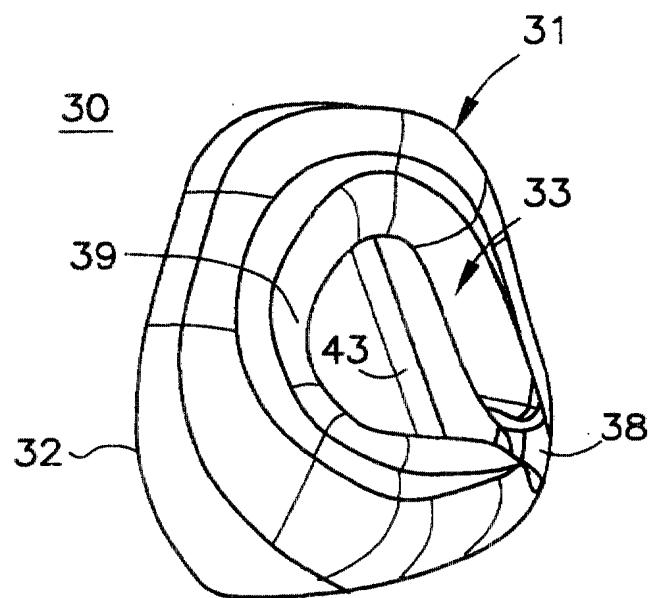
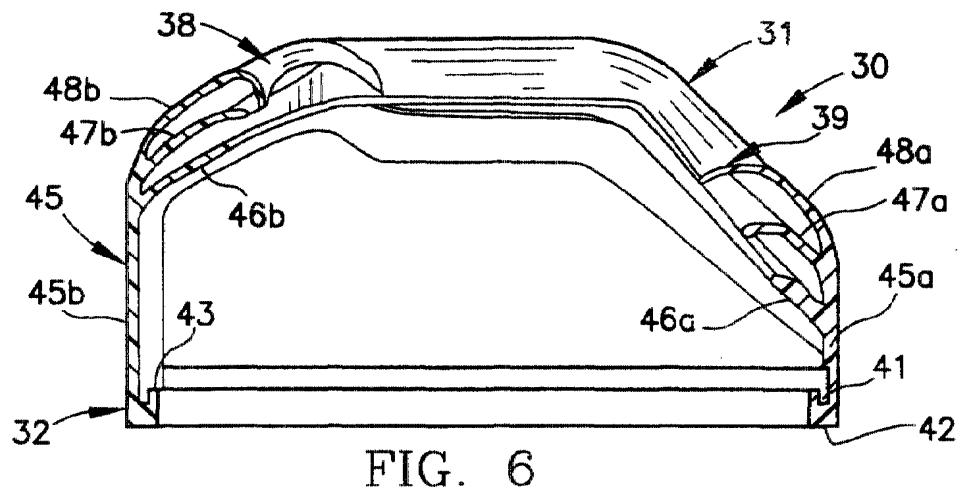
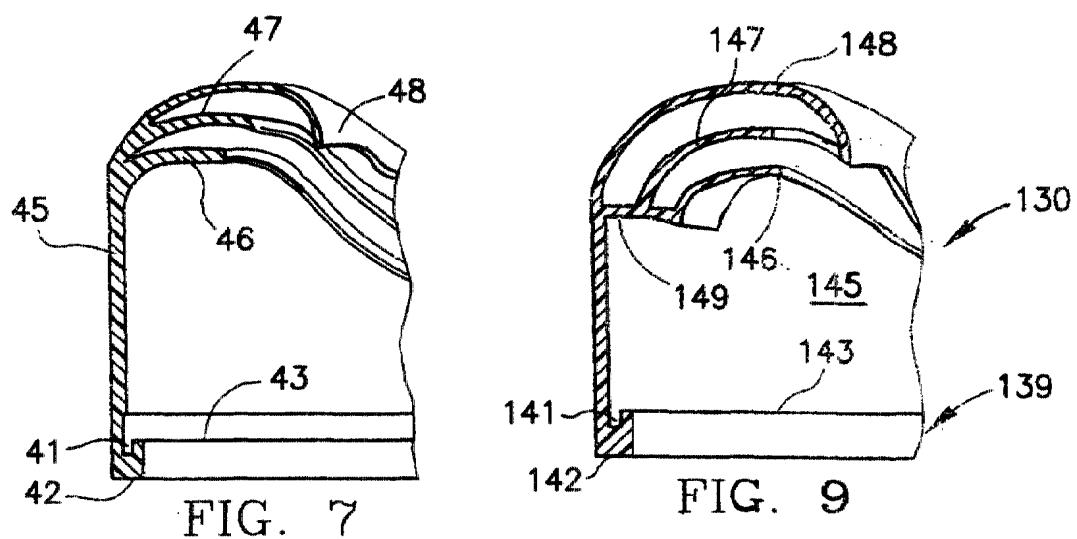
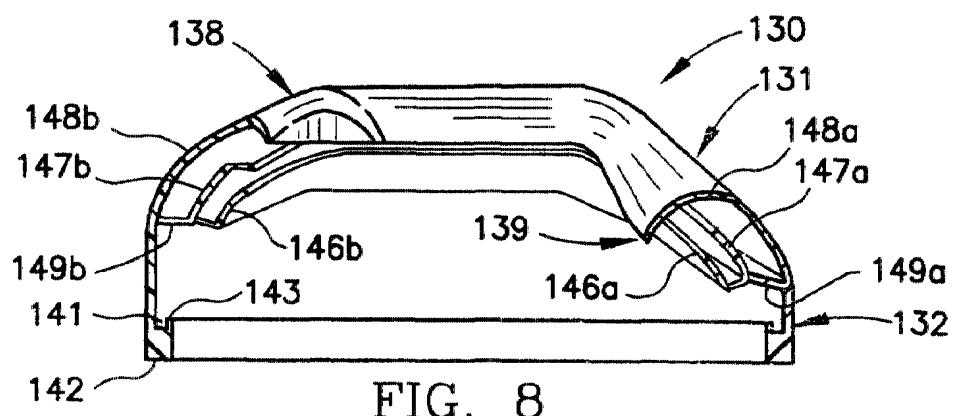


FIG. 5



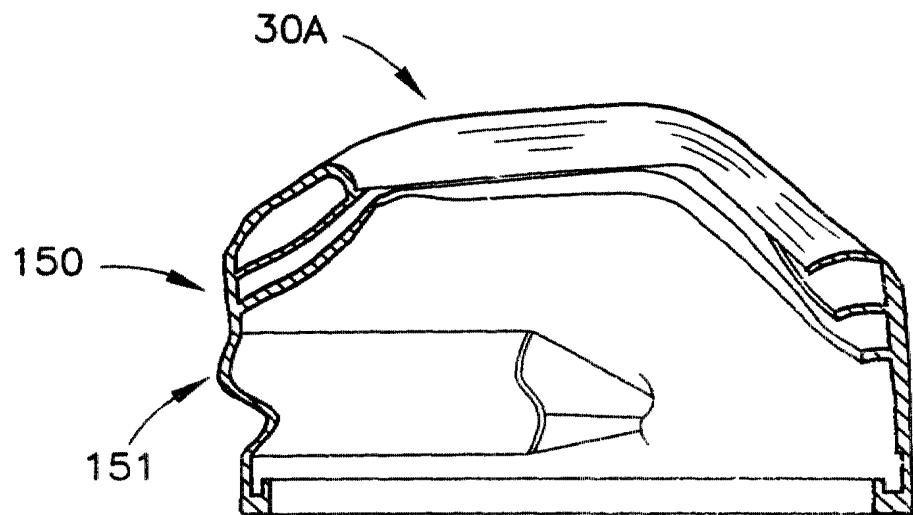


FIG. 10A

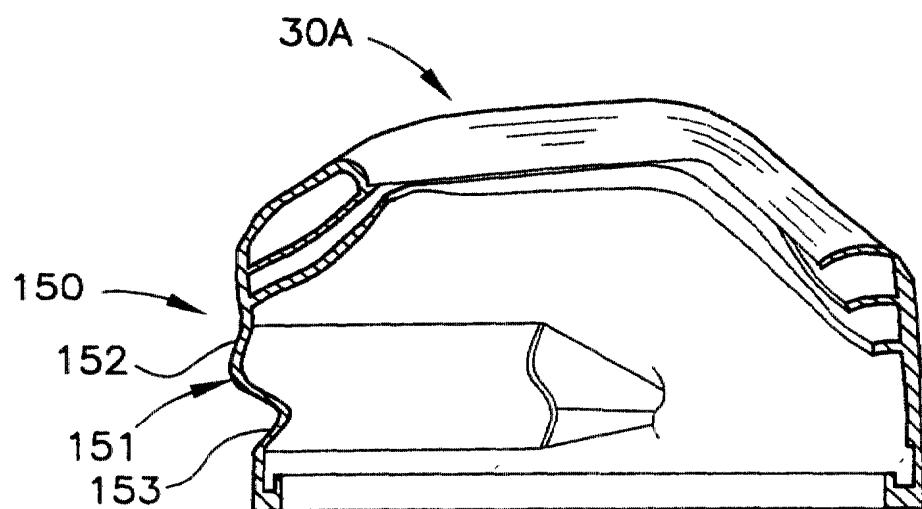


FIG. 10B

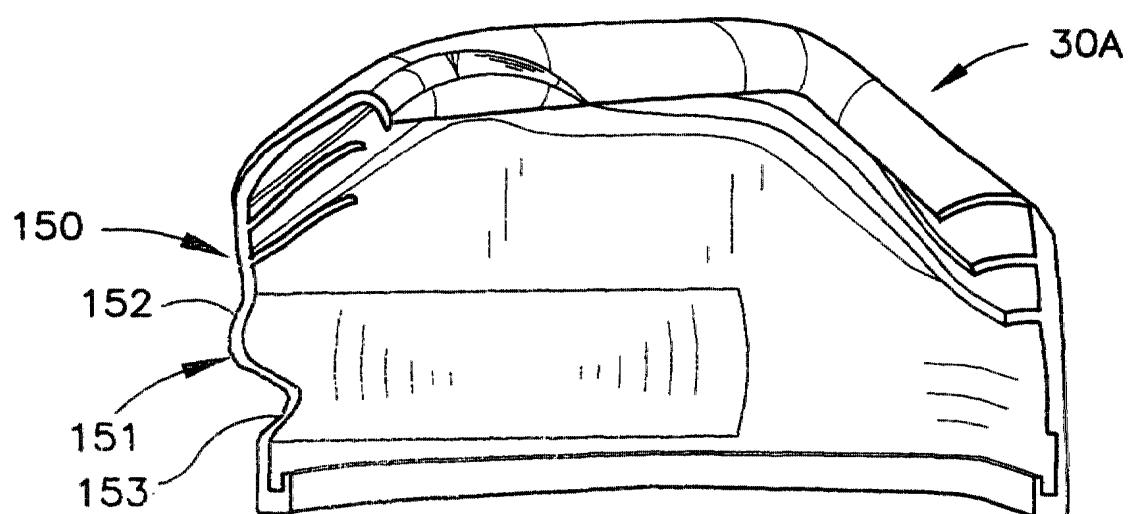


FIG. 11



European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 02 25 3472

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X	US 6 112 746 A (KWOK PHILIP RODNEY ET AL) 5 September 2000 (2000-09-05) * the whole document *	1,19, 21-23, 25,27-29	A62B18/02 A61M16/06
A	US 6 102 040 A (TAYEBI AMAD ET AL) 15 August 2000 (2000-08-15) * the whole document *	1-29	
A	DE 31 49 449 A (MEDIZIN LABORTECHNIK VEB K) 21 October 1982 (1982-10-21) * the whole document *	1-29	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A62B A61M
<p>The present search report has been drawn up for all claims</p>			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	9 August 2002	Neiller, F	
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 02 25 3472

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
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09-08-2002

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 6112746	A	05-09-2000	AU	1245497 A	05-02-1998
			AU	710733 B2	30-09-1999
			AU	3429397 A	20-02-1998
			WO	9804310 A1	05-02-1998
			DE	29724224 U1	07-09-2000
			EP	0956069 A1	17-11-1999
			JP	2000515784 T	28-11-2000
			US	2002083948 A1	04-07-2002
			US	2002074001 A1	20-06-2002
			US	2002029781 A1	14-03-2002
			US	2002005198 A1	17-01-2002
			US	2002005200 A1	17-01-2002
US 6102040	A	15-08-2000	US	5673690 A	07-10-1997
			AU	709676 B2	02-09-1999
			AU	2345697 A	17-10-1997
			BR	9708251 A	04-01-2000
			CN	1214617 A	21-04-1999
			EP	0906037 A1	07-04-1999
			JP	2000507461 T	20-06-2000
			WO	9735492 A1	02-10-1997
DE 3149449	A	21-10-1982	DD	160727 A3	22-02-1984
			DE	3149449 A1	21-10-1982